

Attorney Docket No.: DC0266US.NP
Inventors: Kitareewan, et al.
Serial No.: 10/564,070
Filing Date: March 3, 2006
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REMARKS

Claims 1-7 are pending in this application. No new matter has been added. Applicants are respectfully requesting reconsideration of the restriction requirement in view of the following remarks.

Claims 1-7 have been subjected to a Restriction Requirement under 35 U.S.C. §121 and §372 as follows:

Group I, claims 2-3, drawn to an agent which destabilizes lysosomes to increase oncogenic or aberrant protein degradation;

Group II, claim 1, drawn to a method for identifying an agent which destabilizes lysosomes to increase oncogenic or aberrant protein degradation;

Group III, claims 4-5, drawn to a method for increasing oncogenic or aberrant protein degradation in cells; and

Group IV, claims 6-7, drawn to a method for treating a disease or condition associated with an oncogenic or aberrant protein.

The Examiner suggests that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Specifically, the Examiner suggests that even though the inventions of these groups require the technical feature of the agent of Group I, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Gandy et al. (US 5,242,932). It is suggested that Gandy teaches agents which modulate or affect

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the intracellular trafficking and processing of proteins in the mammalian cell, particularly useful agents are chloroquine and related derivatives, such agents can be utilized to inhibit production of Alzheimer type amyloidosis (abstract). The Examiner concludes that the inventions are not so linked by the same or a corresponding technical feature as to form a single general inventive concept. Applicants are required to elect one of the species to be examined.

It is further suggested that the application contains claims directed to more than one species of the generic invention which are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

For anyone of Groups I-IV elected, Applicants are required to elect:

(i) a single agent compound species selected from the compounds recited in claims 3, 5 or 7, or a compound specifically disclosed, such as at pp. 10-12 of the instant specification.

If Group IV is elected, Applicants are required to elect:

(ii) a single disease or condition specie; elect a single species from the diseases/conditions disclosed in the specification (e.g., from p. 14, last paragraph).

Applicants respectfully disagree and traverse this restriction requirement and election of species. The present invention relates to compositions and methods for destabilizing lysosomes to *increase the degradation* of oncogenic or aberrant proteins for the prevention and treatment of disease.

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The '932 patent teaches that lysosomes may be involved in amyloid precursor protein (APP) processing. This reference teaches that while untreated cells exhibit a decrease in APP levels attributable to the conversion of mature APP to secreted forms as well as proteolytic degradation unassociated with secretion, that chloroquine treated cells have a delay in the conversion of mature APP to secreted forms with little effect on degradation (col. 11, lines 47-57). A small decrease in the recovery of secreted APP was noted when chloroquine was present; however, it was contemplated that chloroquine catalyzed the proteolysis of APP in the medium (col. 12, lines 4-16). Therefore, the effect claimed the instant invention and that of the '932 patent are distinct; the '932 patent contemplates decreasing processing whereas the instant invention requires increasing degradation. Therefore, the subject matter of the present invention is novel and non-obvious and unity of invention exists.

Moreover, Applicants respectfully traverse the required election of species in this case. In particular, in so far as Group II is a screening claim, limitation of claim 1 to a particular species is counterproductive to the goal of screening for novel agents that destabilize lysosomes. Therefore, reconsideration of this species election is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group II, claim 1, drawn to a method for identifying an agent which destabilizes lysosomes to increase oncogenic or aberrant

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protein degradation, with traverse. Applicants also elect chloroquine or a derivatives, analog, or enantiomer thereof as recited in claim 3 as the species of agent compound, with traverse.

Respectfully submitted,



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Date: **August 19, 2009**

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